

# Proposed Integrated Approach to Pesticide Evaluation

## Pest Management Regulatory Agency

YOUR HEALTH AND SAFETY... OUR PRIORITY.



## Introduction

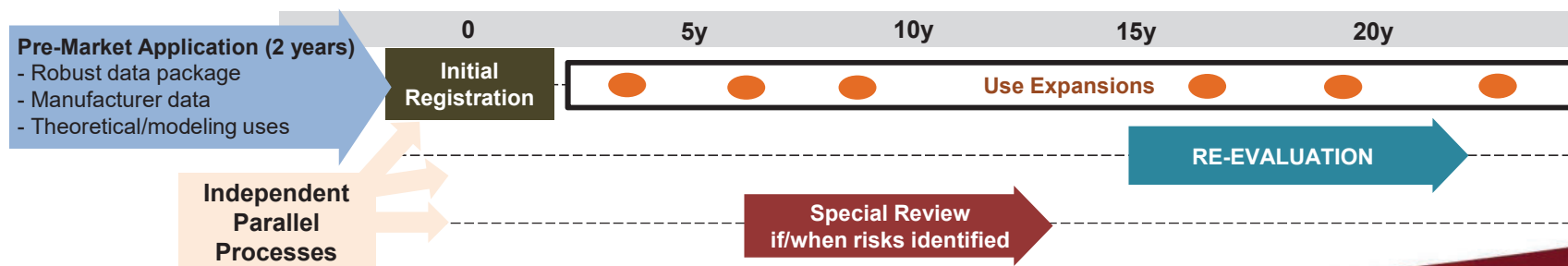
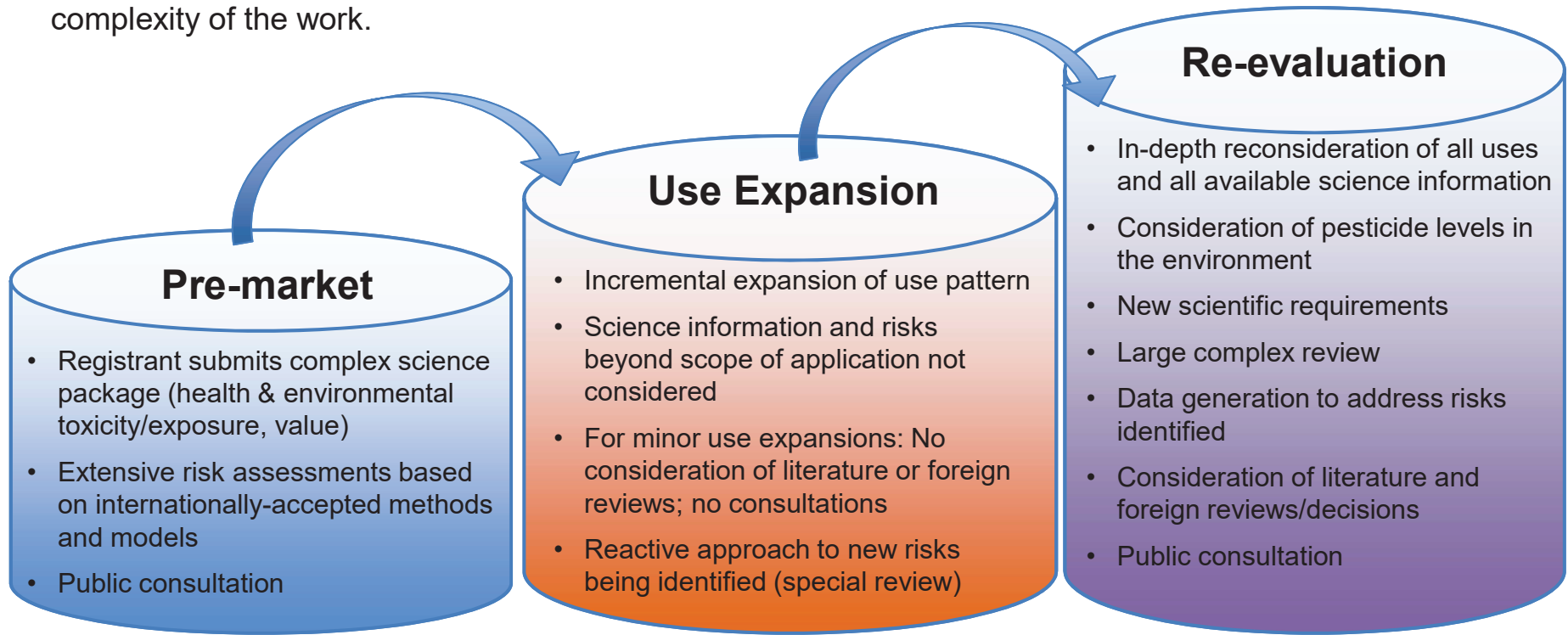
- Following internal analysis and broad consultations to understand stakeholder's issues and concerns, PMRA has developed a proposed integrated approach to pesticide evaluation.
- The new approach is a key component of the Health Minister's December 2019 mandate:
  - “With the support of the Minister of Agriculture and Agri-Food and the Minister of Environment and Climate Change, work to ensure that the Pest Management Regulatory Agency makes timely science-based decisions to support the safe and sustainable use of effective pesticide products in Canada.”
- The purpose of this presentation is to give an overview of the proposed integrated approach and gather feedback from stakeholders.

# Context

- The current pesticide re-evaluation program is unable to meet legislated requirements for a 15-year cyclical review, with current resource levels. Within the existing framework, the re-evaluation backlog will continue to grow, despite the efforts and process improvements PMRA has made to date.
- Considering that re-evaluations generally result in risk mitigation, a backlog in re-evaluations allows potentially unacceptable risks to health and the environment to continue unabated.
- Efforts to address the re-evaluation backlog have introduced challenges in meeting pre-market review performance timelines.
- Broader changes are needed to reduce the burden of the re-evaluation program while improving health and environmental protection.

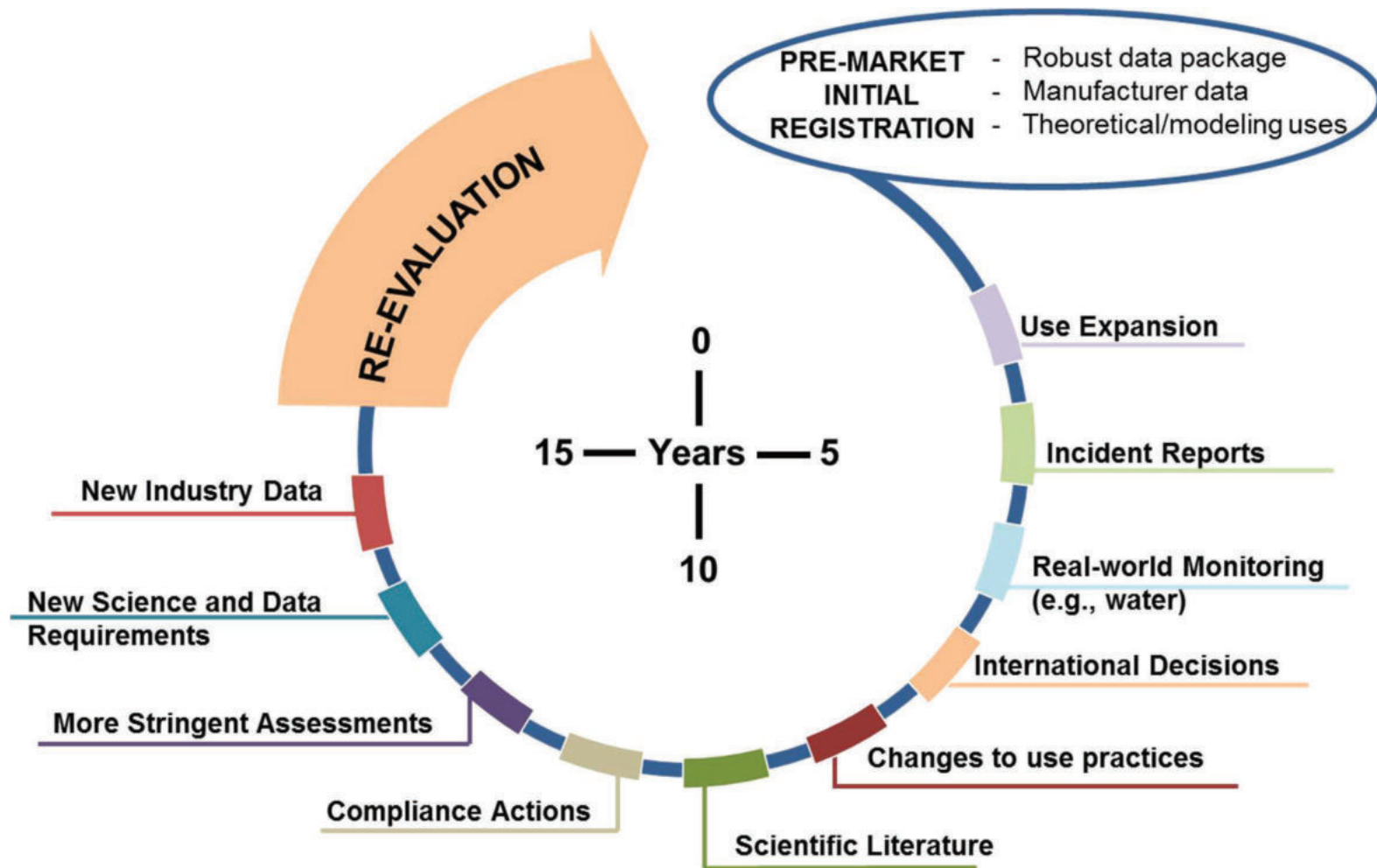
# Current Pesticide Program

Pesticide reviews under different programs proceed in silos, resulting in a lack of integration between streams. Broader consideration of risks may not occur until re-evaluation, thereby increasing scope and complexity of the work.



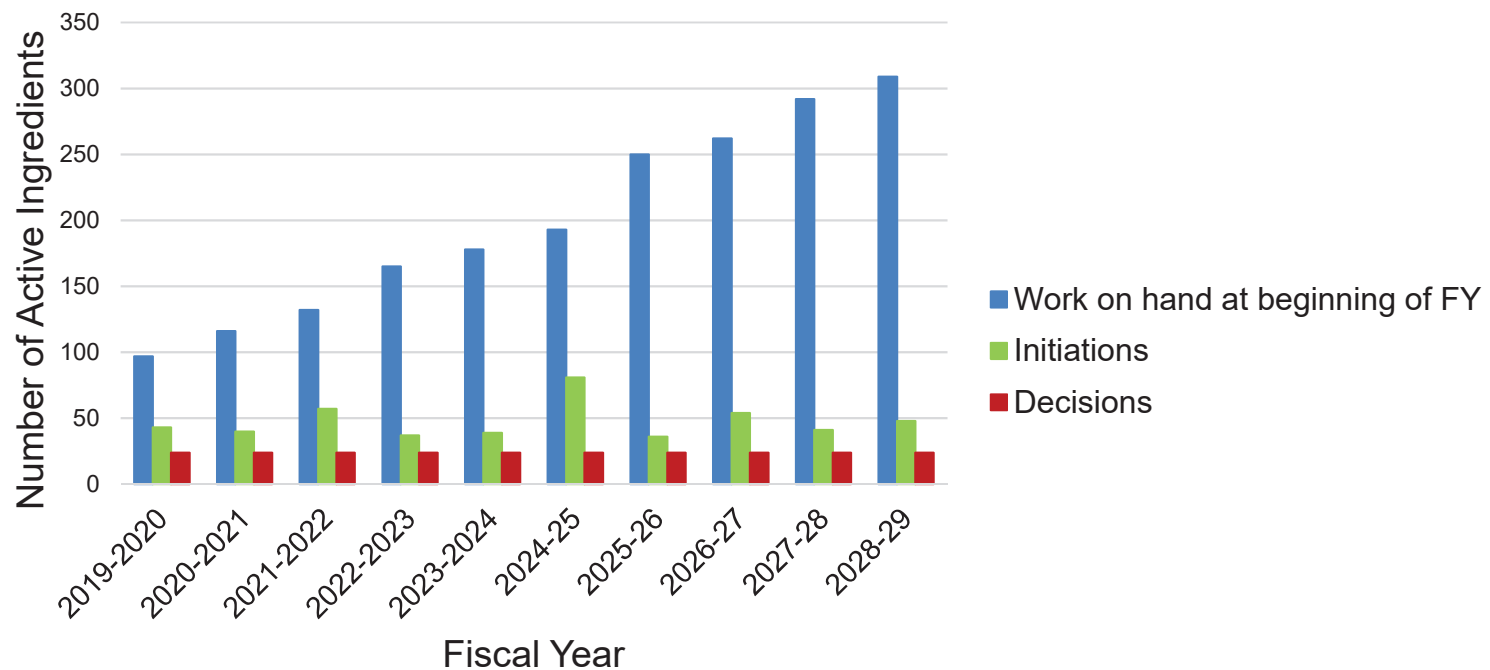
# Pesticide Regulatory Lifecycle

The complexity and extent of available information increases after initial registration



# Re-evaluation Workload

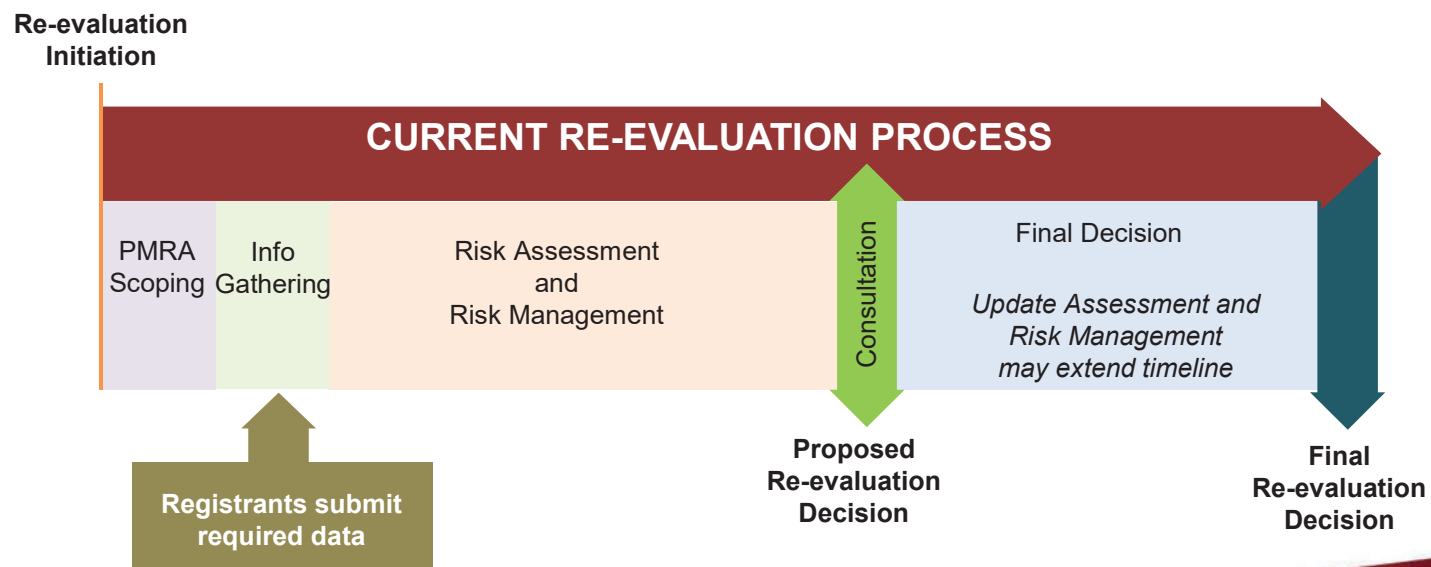
- Legislatively required cyclical initiations are increasing, as are the complexity of the scientific assessments. The resulting workload to meet the PCPA requirements is outpacing decision-making capacity at current resource levels.
- New re-evaluations are adding to an existing backlog of re-evaluations



# Current Re-evaluation Process

## Key issues with the current process

- **Health and environmental risks are not being addressed in a timely manner**
- Key information is not available to PMRA at the right time
- Re-evaluations are highly complex with extensive new information to be considered
- Substantial updates to assessments are required between the proposed and final decision
- Does not align effectively with international partners
- Limited engagement early in re-evaluation process
- No risk-based prioritization of workload



# Key Re-evaluation Challenges and Opportunities



**Workload:** Increasing workload leads to growth in backlog



**Data:** Key information is not available to PMRA at the right time



**International collaboration:** Key part of the process but U.S. and other partners are looking to Canada for leadership



**Transparency and process improvement:** Stakeholder dissatisfaction with the current process model for re-evaluations

## Opportunities

Reduce the burden of the re-evaluation program by adopting an approach of continuous oversight and management of risks

Reduce reliance on re-evaluations for mitigating risks

Improved control and oversight: onus on registrants, increased engagement, stricter controls of data submission, timely availability and review of monitoring and use information

Process improvements for increased efficiency

# Integrated Pesticide Program: Applications

## Leverage scientific assessments completed for new applications to inform re-evaluation needs

- Certain applications requiring substantive risk assessments would be used as pulse check to determine if broader consideration of the active ingredient is needed
- Improve understanding of risks and value of the active ingredient
  - Consideration of new information
  - Are there any emerging risk issues that require review
  - Information needs for next application or re-evaluation
  - Changes to how the products is used
- Leverage existing work without delays to application timelines
- Take action when needed
  - Special review, Signal future data needs

## Expected Outcomes

Identify and address emerging risk sooner

Data needs identified in advance of re-evaluation

Re-evaluation timeline may be adjusted

Reduces re-evaluation complexity

Contributes to timely re-evaluation decisions

# Integrated Pesticide Program: Renewal Process

**Expanded renewal process as a pulse check to collect and consider information throughout the pesticide lifecycle.**

- Requirements for registrants to submit key information
- Strengthened post-market surveillance capacity
  - Water-monitoring, bio-monitoring
  - Canadian use and other value information
  - Sales trends
  - Incident reports, Compliance
- Review the risk assessment on file
  - Have assumptions or exposures changed since previous review?
  - Consideration of new information available
  - Are there any emerging risk issues that require review
  - Information needs for next application or re-evaluation
- Take action when needed
  - Special review, Signal future data needs

## Expected Outcomes

Continuous evaluation approach to identify emerging risk issues and improve understanding of risks

Risks addressed sooner

Data needs identified in advance of re-evaluation

Reduces re-evaluation complexity

Contributes to timely re-evaluation decisions

Registrant required to submit information

**Expanded  
Renewal  
Process**

PMRA surveillance of pesticides in market

## Considerations

- **Continuous evaluation approach identifies and addresses risks sooner to improve overall protection of health of Canadians and the environment**
  - Allows data development before re-evaluation; reduces delays and rework; transparent; predictable
  - Builds on, and surpasses, international trends for more proactive oversight of pesticides
  - Cyclical re-evaluations would continue as a backstop. Re-evaluations are less complex.
- **Re-distributes workload but does not eliminate it**
  - Does not address existing backlog of re-evaluations
  - Results in delaying lower risks and bringing emerging risks forward in schedule
- **Risk-based approach to management of pesticides**
  - Emerging risks addressed sooner